EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 23, 2019

Via Email

John C. Bostic
Assistant United States Attorney
john.bostic@usdoj.gov

Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear John:

Pursuant to the Court's July 19, 2019 Order, this letter is to advise you of the status of the U.S. Food and Drug Administration's ("FDA") production of documents responsive to Defendants' motion to compel in the above-referenced case.

FDA has taken great efforts to meet the Court's October 2, 2019 deadline and barring any unforeseen personnel or technical issues, it anticipates that it will be in substantial compliance with that deadline, as detailed further below. As you know, since the Court's Order, FDA has made four productions to the parties totaling over 2,400 documents / 25,000 pages. FDA also expects to make a substantial production to the parties on or before October 2 of approximately 2,530 documents. The number of documents and pages is likely to be more, as approximately 500 additional documents marked as responsive and non-privileged, are currently undergoing second-level review.

Following the Court's July Order, FDA continued its manual review and production of documents while, at the same time, it investigated access to technology-assisted methods to facilitate its review. Through a special arrangement with its parent agency, the U.S. Department of Health and Human Services, FDA was able to obtain access to an electronic document review platform and has, since August, been using that platform to de-duplicate, review, and ultimately produce documents responsive to the motion to compel. This has helped to streamline this massive review: for example, out of 151,180 documents from over 65 custodians collected in response to the subpoena issued in the SEC matter, 75,181 were identified via metadata as exact duplicates.[1] Additionally, FDA was able to segregate the remaining documents into the following two buckets:

[1] For example, if email A was sent to Persons 1, 2, and 3, the platform was able to automatically determine that email A for Person 1 should be loaded for review (and list Persons 2 and 3 as additional custodians) without actually loading three copies of email A to the database for review, thereby cutting the review time for email A by two-thirds.

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1) Documents potentially responsive to the motion to compel categories that appeared to be unique[2]: 4,602
2) Documents potentially responsive to the motion to compel categories that, via a textual analysis, appear to be duplicates of documents already in the possession of the parties because of prior productions of FDA documents, or duplicates of each other[3]: 39,803

Since bucket one contains documents that appear to be distinct from those previously produced, FDA has made review and production of documents from that bucket its top priority. As explained above, of the 4,602 documents in bucket one, FDA expects that the parties will receive as many as 3,000 responsive, non-privileged documents on or before October 2.

While the FDA has been focusing its efforts on bucket one, it has also been reviewing bucket two in an effort to identify any non-duplicate documents in that bucket. Based on the progress to date, FDA has already eliminated 32,470 of the documents in the second bucket as duplicates. 7,333 remain in further de-duplication or responsiveness review. Many of these documents, while not exact duplicates of previously produced documents, are so similar to each other or previously-produced documents that they actually provide no new substantive information. Nonetheless, as FDA identifies unique documents (even those that actually provide no new substantive information), those documents are added to the review population. FDA is aiming to produce the responsive, non-privileged documents from this 7,333 subset on or before October 2.

Although it is difficult for FDA to determine at this point how many responsive, non-privileged documents will remain to be produced after October 2, if FDA is not able to produce all responsive, non-privileged documents from current bucket two by that time, the number left to produce should be no greater than what remains in that bucket, i.e., 7,333. Notably, the number is likely to be substantially fewer than that due to continued efforts to de-duplicate documents from the second bucket and as a result of responsiveness and privilege review.

It is likely that the following sets of documents will not be included in FDA's October 2 production:

- Documents from FDA's Office of the Chief Counsel, on the basis that all, or the vast majority, of the documents not already captured in productions from other custodians are protected by the attorney-client privilege and/or work product doctrine;
- Documents identified as containing foreign language or technical issues, such as stub files (i.e. archived files that need to be restored from FDA's network, re-loaded to the platform, and then reviewed);
- A subset of documents from two custodians who were former employees, due to technical difficulties during collection. Among other issues, a corrupt Outlook

[2] Not including documents from FDA's Office of the Chief Counsel
[3] Not including documents from FDA's Office of the Chief Counsel

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Data File (".pst file") needed to be repaired; emails needed to be located in backup tapes and restored prior to searching; and a data collection system crashed. Notably, though, these technical difficulties affected only (a) one of eight .pst files from one custodian (the other seven were transferred to the review platform), and (b) a subset of documents for another custodian, who FDA believes is unlikely to have documents responsive to the motion to compel.

FDA has devoted extensive resources to this review in an effort to meet the Court's deadline and believes that, with the documents that it will produce on or before October 2, the parties will have received the vast majority of information responsive to the Court's July 19, 2019 Order. The review undertaken to date demonstrates that any remaining documents that FDA will continue to work on after October 2 are unlikely to contain novel information, even if they are not exact duplicates of previously produced documents. The primary reason that FDA anticipates that it will not be in strictly full compliance (rather than substantial compliance) with the Court's October 2 deadline is primarily due to the sheer volume of the data and the delay caused by having to retrieve backups of damaged files. FDA, of course, understands the time sensitivities for the parties, and thus will continue its diligent efforts to review and produce responsive, non-privileged documents. Barring further technical difficulties, FDA anticipates that it can complete its document production in this matter by approximately October 28.

I trust that this letter provides you with the information required by the Court's July 19, 2019 Order. FDA will continue to work as expeditiously as possible to provide the parties with the documents subject to the Court's Order, as set forth above.

Sincerely,

Marci B. Norton AMK

Marci B. Norton
Senior Counsel